DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 8, 2015

AMO Manufacturing USA, LLC
Mr. Rodney Huang
Regulatory Affairs PDP
510 Cottonwood Drive
Milpitas, CA 95035

Re: K141852
Trade/Device Name: iFS Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Powered Laser Surgical Instrument
Regulatory Class: Class II
Product Code: GEX, HNO
Dated: November 24, 2014
Received: November 26, 2014

Dear Mr. Huang:

This letter corrects our substantially equivalent letter of January 6, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown

Device Name
iFS Laser System

Indications for Use *(Describe)*

- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea, penetrating and/or intrastromal
- In lamellar IEK and corneal harvesting
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- In the creation of a lamellar cut/resection of the cornea for lamellar IEK and for the creation of a penetrating cut/incision for penetrating IEK
- In patients undergoing ophthalmic surgery or other treatment requiring the creation of corneal channel for placement/ insertion of a corneal inlay device

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5
510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Applicant: AMO Manufacturing USA, LLC
510 Cottonwood Drive
Milpitas, CA 95035
Tel: 408-273-4159

b. Contact Person: Rodney Huang
Regulatory Affairs PDP
510 Cottonwood Drive
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Tel: 408-273-4159
Fax: 408-273-5966
Email: rodney.huang@amo.abbott.com

c. Date of Summary Preparation: July 7, 2014

Name of device, including trade name and classification name:

Trade/Proprietary Name: iFS Laser System
Common/Usual Name: Laser
Classification Name: Powered Laser Surgical Instrument
Classification Code(s): GEX (21 CFR 878.4810)
HNO (21 CFR 886.4370)

Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

510(k) #	Trade Name	Manufacturer
K131207	FEMVTO LDV Z6 Femtosecond Surgical Laser	SIE AG, Surgical Instrument Engineering
K113151	iFS Laser System	AMO Manufacturing USA, LLC

A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The iFS Laser System is an ophthalmic surgical laser designed for use as an ophthalmic surgical laser indicated for use as follows:

- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea, penetrating and/or intrastromal
- In lamellar IEK and corneal harvesting
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- In the creation of a lamellar cut/resection of the cornea for lamellar IEK and for the creation of a penetrating cut/incision for penetrating IEK
- In patients undergoing ophthalmic surgery or other treatment requiring the creation of corneal channels for placement/insertion of a corneal inlay device

The iFS Laser System uses focused femtosecond laser pulses to create incisions and separate tissues in the cornea. Corneal dissection with the iFS Laser is achieved through precise individual micro-photodisruptions of tissue, which are controlled by repeatedly repositioning the laser focus. The light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. The surgical effect is produced by scanning thousands of individual pulses per second to produce continuous incisions or tissue separation. These laser pulses are delivered through a disposable applanation lens that contacts the cornea while fixating the eye under low vacuum.

Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The technological characteristics of the iFS Laser System are substantially equivalent to those cleared indications under K131207 and K113151 for corneal resections and incisions. The subject and predicate iFS Laser System (K113151) and the Femto LDV Z6 Femtosecond Surgical Laser (K131207) share the same design principle and mode of operation in that they all deliver femtosecond pulses through a computer-controlled delivery system to produce a pattern of photodisruption to create cuts / separation in ophthalmic tissue. The means of fixation of the patient contact portion of the devices are all substantially equivalent in that a suction vacuum affixes a suction ring to the corneal surface prior to use.

No changes to the iFS Laser System operating principles, hardware, system specifications, or disposable applanation lens were required for the additional indication for use in patients requiring the creation of corneal channels for placement/insertion of a corneal inlay device. Software updates were required to include the addition of an inlay channel pattern and the associated graphical user interface functionality

Brief summary of nonclinical test and results:

Verification and validation of the software updates were documented per FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005, and demonstrated that the functional and safety critical requirements are fulfilled and no outstanding safety critical issues remain open.

The iFS Laser System underwent medical electrical equipment testing and was in compliance with applicable safety standards as listed in the following table.

Standard	Description
IEC 60601-1:2005 3rd edition	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2007 3rd Edition	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-2-22:2007 3rd Edition	Medical Electrical Equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Laboratory verification bench studies evaluated the channel widths, depths, and cut quality using glass microscope slides, Agarose gel, and porcine eyes, respectively. The acceptance criteria for depth were identical to that previously used to establish the acceptable performance of the currently available resection patterns. These studies demonstrated the acceptable performance of the iFS Laser System in creating corneal channel resection patterns associated with the proposed indication for inlay channels.